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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,043	04/27/2005	Heimo Ylanen	TUR-166	7938
32954	7590	01/12/2009		
JAMES C. LYDON 100 DAINGERFIELD ROAD SUITE 100 ALEXANDRIA, VA 22314			EXAMINER WIESE, NOAH S	
			ART UNIT 1793	PAPER NUMBER
			MAIL DATE 01/12/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/530,043

**Applicant(s)**

YLANEN ET AL.

**Examiner**

NOAH S. WIESE

**Art Unit**

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**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-21 and 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 12-21 and 23 is/are allowed.
- 6) ☒ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

***Status of Application***

1. Acknowledgement is made of amendments filed 10/23/2008. Upon entering the amendments, claim 12 is amended, claim 22 is cancelled, and claim 23 is added.

The claims 12-21 and 23 are pending and presented for the examination.

***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 12-13, 16-18, and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brink et al (US 6054400).

Regarding **claim 12**, Brink et al teaches a bioactive glass composition that contains the same components of composition of claim 12. The components are taught in ranges that are broader than the ranges of claim 12, but encompass said ranges (see Brink claims 1 and 4, compositions reproduced below).

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SiO <sub>2</sub>	53-60 wt-%
Na <sub>2</sub> O	0-34 wt-%
K <sub>2</sub> O	1-20 wt-%
MgO	0-5 wt-%
CaO	5-25 wt-%
B <sub>2</sub> O <sub>3</sub>	0-4 wt-%
P <sub>2</sub> O <sub>5</sub>	0.5-6 wt-%

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SiO <sub>2</sub>	53-60 wt.-%
Na <sub>2</sub> O	0-19 wt.-%
K <sub>2</sub> O	1-17 wt.-%
MgO	3-5 wt.-%
CaO	5-22 wt.-%
B <sub>2</sub> O <sub>3</sub>	0-4 wt.-%
P <sub>2</sub> O <sub>5</sub>	0.5-6 wt.-%

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While the ranges taught by Brink are broader than those of the claim, they are not so broad as to make the Brink glasses materially different composition. Indeed, the Brink glasses are specifically taught to be of the same type as those of instant claims, that is, bioactive glasses. This indicates that the compositions of instant glasses are optimizations of the broader compositions of Brink, rather than materially different glasses. Therefore, glass compositions containing the components of instant claims in the claimed ranges could be obtained through the routine optimization and experimentation with the similar compositions taught by Brink.

The glass system on which the Brink glasses and those of instant claims are based, SiO<sub>2</sub> - Na<sub>2</sub>O - CaO - P<sub>2</sub>O<sub>5</sub>, is a very well known system for bioglasses. See for example US 7040960, US 5648301, and US 5401693. Because it is well known in the art that successful bioglasses should contain the above components in the approximate ranges, and the Brink glasses broadly meet these known attributes, the experimentation and optimization of the Brink teachings would be very extensive. Thus, one of ordinary skill would have had motivation and ability to optimize the Brink glasses, and doing so would produce

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glasses meeting the limitations of claim 12. The claim is therefore obvious and not patentably distinct over the prior art of record.

Regarding **claim 13**, Brink teaches that the  $\text{SiO}_2$  is optimally present in the amount of 54-56 wt% (see claim 5).

Regarding **claim 16**, Brink teaches that the glass compositions can be coated on a device (see column 4, lines 34-40).

Regarding **claim 17**, Brink teaches that the bioactive glass can be used in an implantable device (see column 5, lines 7-20).

Regarding **claim 18**, Brink teaches that the bioactive glasses can be used as fibers (see column 4, lines 34-40).

Regarding **claim 20**, Brink teaches that the bioactive glass can be made into a porous device (see column 4, lines 34-40). Brink does not explicitly teach how the porosity is introduced into the glass. However, this is a product-by-process limitation and as such, is not given patentable weight to the product claim 20. As shown above, Brink teaches bioactive glass compositions that can be routinely optimized to meet the limitations of instant claims and can be used in porous devices. Because Brink teaches all of the product limitations of claim 20, the additional process limitation does not render the claim patentably distinct over the prior art of record.

Regarding **claim 21**, Brink teaches that the bioactive glass can be used for tissue implants, which are tissue engineering devices (see column 4, lines 34-40).

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4. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brink et al (US 6054400) in view of Bauer et al (US 5401693).

Regarding **claim 14**, the claim differs from Brink et al because Brink does not teach that alumina is included in the bioactive glasses. However, the use of alumina in these types of bioactive glass systems was known in the art at the time the invention was filed.

Bauer et al teaches glass fibers made from bioactive glass. As discussed above, the glasses taught in Bauer are of the same  $\text{SiO}_2 - \text{Na}_2\text{O} - \text{CaO} - \text{P}_2\text{O}_5$  system as those of Brink et al. Bauer further teaches that small amounts of  $\text{Al}_2\text{O}_3$  are present in the bioactive glass composition (see column 6, lines 25-34). The  $\text{Al}_2\text{O}_3$  acts as a network former in the bioglasses, which leads to increased strength and resiliency (see column 3, lines 29-39). One of ordinary skill in the art would have been motivated to include the small amount of  $\text{Al}_2\text{O}_3$  in the Brink glass if small increases in strength properties were desired. The teachings of Bauer et al show that this inclusion was known in the same type of bioactive glass system as is used in Brink, so reasonable success would be expected. The modification of Brink in view of Bauer would lead one of ordinary skill to include  $\text{Al}_2\text{O}_3$  in amounts of less than 1 wt% to the Brinks glasses. Therefore, claim 14 is obvious and not patentably distinct over the prior art of record.

Regarding **claim 15**, it would be obvious to one of ordinary skill that a decrease in  $\text{Na}_2\text{O}$  or  $\text{K}_2\text{O}$  could be replaced by  $\text{Al}_2\text{O}_3$  or  $\text{B}_2\text{O}_3$ , given the teachings of Brink and Bauer.

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5. Claims 19 and 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brink et al (US 6054400) in view of Young et al (US 3904425).

Regarding **claim 23**, Brink et al teaches that the glasses are made by melting the batch to a temperature of 1300-1600°C, cooling, and then remelting the batch at the same temperature (see column 6, lines 45-55). Brink teaches that the glasses can be crushed between heatings (see column 4, lines 34-40 and column 14, lines 58-62). Claim 23 differs from Brink et al because Brink does not teach the time at which the glass is held at the elevated temperatures (fining), or the time at which the glass is left at ambient temperature between heatings. However, these times were known in the art at the time the invention was filed.

Young et al teaches a method of producing glasses comprising melting the glass batch, fining at a temperature of 1371°C for 1-3 hours, and then cooling the glass to room temperature overnight (see column 3, lines 58-66). While the composition of the Young glass is somewhat different than that of the Brink glasses, the Young glass contains many of the same elements and is similar enough that the methods are analogous. One of ordinary skill would have been motivated to take the fining and cooling times from the Young method because these times are not taught specifically by Brink, which would cause one to look elsewhere for the variables. Young teaches a method for preparing glasses similar to the Brink glasses and melted at similar temperatures, and so one would be motivated to use Young for modification. The temperatures and melting times taught by Young are used because they are adequate for the homogenous

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melting, fining, and casting of the glass composition. These are advantageous effects that one would seek when creating a practical method for the Brink glasses. The modification of Brink in view of Young teaches all of the method limitations of claim 23, and thus the claim is obvious and not patentably distinct over the prior art of record.

Regarding **claim 19**, the claim differs from Brink et al because Brink does not explicitly teach that the glass can be formed into a sheet. But forming sheets of glass compositions is well known in the glass arts. The teachings of Young show that forming glass sheets is well known (see columns 3-4, lines 65-17). One would have been motivated to form a sheet from the Brink glasses because this configuration would be useful for substrates or for testing samples, the purpose for which the sheets are used in the Young patent. Thus, forming a sheet from the Brink glass compositions would have been obvious to one of ordinary skill in the art, and the claim is patentably indistinct over the prior art of record.

### ***Applicant's Arguments***

6. Applicant's arguments filed 10/23/2008 have been fully considered but are not persuasive.

Applicant argues that no single embodiment of the Brink glasses meets all of the limitations of instant claims. While this is true, Brink teaches bioactive glasses comprising all of the components of instant claims in ranges that closely encompass those of instant claims. Further, as shown in Table 1 and as recognized by applicant, Brink teaches specific embodiments that meet the



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instant claim limitations for most of the components and are very close for the other components. In the example 27 cited by applicant, the  $\text{MgO}$  and  $\text{P}_2\text{O}_5$  components are slightly higher than the claimed ranges. However, it is abundantly clear that the full ranges for these components taught by Brink encompass the claimed ranges, and thus one of ordinary skill in the art would have had motivation to use lower amounts of  $\text{MgO}$  and  $\text{P}_2\text{O}_5$  through routine experimentation.

Applicant's arguments regarding the specific properties of the claimed compositions show that these properties are unique to these ranges, but do not show any reason that one of ordinary skill would not have used these ranges given they are suggested by the Brink teachings. Applicant has provided no evidence or rationale why one of ordinary skill would not have used the full ranges taught by Brink, and thus the prima facie case of obviousness is maintained.

Applicant further argues that the modification of Brink et al in view of Bauer et al does not teach the compositions of claims 14 and 15 because Bauer et al does not disclose or suggest that the claimed composition would possess superior resistance to crystallization, and because the Bauer compositions are "less relevant" to the claimed compositions. However, these arguments are not persuasive because they do not show that the motivation to modify Brink in view of Bauer would not be present. As previously discussed, one of ordinary skill in the art would find motivation to use  $\text{Al}_2\text{O}_3$  in the Brink compositions because

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Bauer teaches similar bioglass compositions using this compound as a network former. Therefore, applicant's contentions are not persuasive.

Applicant argues that the modification of Brink in view of Young does not teach the method of new claim 23 because the composition of the claim is not taught by Brink or Young. However, as discussed above, routine optimization of the Brink teachings would lead to the claimed compositions. Applicant further argues that the Young method is for use with a type of glass that is different from that taught by Brink. However, as discussed in the previous office action, the glasses contain most of the same components and are therefore analogous for processing purposes. Further, there is nothing in the Young patent to indicate that it would not be usable with compositions such as those of Brink. Therefore, the motivation to combine as discussed in the previous office action is still valid, and this line of argument is not persuasive.

### ***Conclusion***

7. All the pending claims are rejected.
8. Applicant's arguments are not persuasive, and the previously issued grounds of rejection are maintained. The new claim 23 is rejected under the same grounds as the previously presented claim 22, because claim 23 is the independent re-writing of claim 22. Therefore, **THIS ACTION IS MADE FINAL.**
9. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory

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period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NOAH S. WIESE whose telephone number is (571)270-3596. The examiner can normally be reached on Monday-Friday, 7:30am-5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry Lorengo can be reached on 571-272-1233. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Noah Wiese  
January 7<sup>th</sup>, 2009  
AU 1793

/Karl E Group/  
Primary Examiner, Art Unit 1793